ARC 0485C

HUMAN SERVICES DEPARTMENT[441]

Adopted and Filed

Pursuant to the authority of Iowa Code section 249A.4, the Department of Human Services amends Chapter 77, "Conditions of Participation for Providers of Medical and Remedial Care," and Chapter 79, "Other Policies Relating to Providers of Medical and Remedial Care," Iowa Administrative Code.

These amendments change Medicaid payments for drugs.

There are two components to pharmacy reimbursement for a drug: the ingredient cost and a dispensing fee. The current Iowa Medicaid reimbursement methodology for drug ingredient cost incorporates the average wholesale price (AWP) published by Medi-Span minus a percentage, upper payment limits established by the federal Medicaid agency, state-set maximums, and the provider's usual and customary charge. Unless payment is made based on the pharmacy's usual and customary charge, a dispensing fee is added to the ingredient cost to cover the pharmacist's professional services and costs associated with transferring the drug to a Medicaid member. The dispensing fee is currently set at $6.20.

The amendments implement an average actual acquisition cost (AAC) reimbursement methodology for all drug ingredient costs, replacing the AWP and state-set maximums and using a survey of pharmacy invoices to determine the average AAC. Enrolled pharmacies are required to provide drug acquisition cost invoice information. In cases where AAC is not available, wholesale acquisition cost (WAC) published by Medi-Span will be used.

The dispensing fee will be set based on cost of dispensing surveys of Iowa Medicaid participating pharmacies. All participating pharmacies will be required to complete the survey. Based on a survey conducted in June through September, the initial dispensing fee will be $10.02 for all pharmacies including specialty.

Any dispensing or acquisition cost information required to be submitted to the Department that specifically identifies a pharmacy's individual costs will be held confidential.

These amendments comply with 2012 Iowa Acts, Senate File 2336, section 33, which requires that the Department implement ingredient cost reimbursement based on "average acquisition cost," as determined by a survey of the pharmacy invoices, and that the dispensing fee be determined by a cost of dispensing survey. The amendments also comply with proposed federal regulations that define "Actual Acquisition Cost (AAC)" as a reference price for drug reimbursement, use the AAC as an upper payment limit for drugs not subject to upper limits as multiple source drugs, and provide that payments for drugs must be based on surveys of retail pharmacy providers or on other reliable data regarding a pharmacy's actual or average acquisition costs. See 77 Fed. Reg. 5318 at 5320-21, 5366-67 (Feb. 2, 2012).

Licensure requirements for out-of-state pharmacies delivering drugs in Iowa are also clarified, pursuant to Board of Pharmacy rules. See rule 657—19.2(155A).

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 0259C** on August 8, 2012. The Department received comments from two constituents on these amendments.

The first comment was a concern that all information submitted into the Department be held confidential, not just information that might be considered "cost information." The Department responded that these amendments are based on legislative language. In addition, under Iowa's open records law (Iowa Code chapter 22), the Department does not have the authority to keep all survey information specific to a pharmacy confidential. No changes to the amendments were made in response to this comment.

The second comment suggested that the Department should give consideration to the additional costs for dispensing medications to the residents of long-term care facilities. The Department responded that these costs would be considered. The additional reimbursement provided by the current rule for drugs dispensed to a patient in a nursing home in unit dose packaging has been retained. Otherwise, the survey conducted in June through September did not show that the costs for dispensing medications to the

residents of long-term care facilities were significantly different from the costs of dispensing to others. Therefore, no changes to the amendments were made in response to this comment.

The third comment was a request to change the amendments to reflect that pharmacies would provide product availability information, if known. The Department responded that this change provides clarity to the amendments and conforms more closely to the implementing law. Subrule 77.2(2), Survey participation, has been changed to state that pharmacies will make available product availability information only "if known."

The fourth comment asked that the amendments be changed to add a specific time frame for submission of information to the Department. The Department will indicate the time frame for each request, and extensions may also be considered. No changes were made to the amendments specific to the time frame for submission of information.

The Department did strike the word "ingredient" in the amendment to paragraph 79.1(8)"h" in Item 3 to improve clarity of the rule.

Changes have also been made to subrule 79.1(8) to maintain the current drug reimbursement methodology, after February 1, 2013, until federal approval of the new methodology, and to make the new methodology contingent on federal approval. Federal approval had been anticipated before the February 1, 2013, effective date of these amendments. But it now appears that federal approval may not be received until after February 1. The changes made regarding the effective date of the new methodology allow the rule-making process to continue, avoiding any delay in implementing the new methodology upon federal approval.

These amendments do not provide for waiver in specified situations because the state legislation and proposed federal rule do not allow for exclusions and because all pharmacies should be subject to the same reimbursement methodology. The Department has an exception to policy process that may be pursued should a pharmacy determine that its circumstances would merit an exception. Requests for the waiver of any rule may be submitted under the Department's general rule on exceptions at 441—1.8(17A,217).

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 249A.4 and 2012 Iowa Acts, Senate File 2336, section 33.

These amendments will become effective February 1, 2013.

The following amendments are adopted.

ITEM 1. Amend rule 441—77.2(249A) as follows:

441—77.2(249A) Retail pharmacies. ~~Pharmacies~~ Retail pharmacies are eligible to participate ~~providing they are licensed in the state of Iowa or duly licensed in other states~~ if they meet the requirements of this rule.

77.2(1) *Licensure.* Participating retail pharmacies must be licensed in the state of Iowa or duly licensed in another state. Out-of-state retail pharmacies delivering, dispensing, or distributing drugs by any method to an ultimate user physically located in Iowa must be duly licensed by Iowa as a nonresident pharmacy for that purpose.

77.2(2) *Survey participation.* As a condition of participation, retail pharmacies are required to make available drug acquisition cost invoice information, product availability information if known, dispensing cost information, and any other information deemed necessary by the department to assist in monitoring and revising reimbursement rates pursuant to 441—subrule 79.1(8) or for the efficient operation of the pharmacy benefit.

a. A pharmacy shall produce and submit all requested information in the manner and format requested by the department or its designee at no cost to the department or its designee.

b. A pharmacy shall submit information to the department or its designee within the time frame indicated following receipt of a request for information unless the department or its designee grants an extension upon written request of the pharmacy.

c. Any dispensing or acquisition cost information submitted to the department that specifically identifies a pharmacy's individual costs shall be held confidential.

ITEM 2. Amend subrule **79.1(2)**, provider category "Prescribed drugs," as follows:

Provider category	Basis of reimbursement	Upper limit
Prescribed drugs	See 79.1(8)	~~$6.20 dispensing fee effective 8/1/11.~~ ~~(See 79.1(8)*"a," "b,"* and *"e."*)~~ Amount pursuant to 79.1(8).

ITEM 3. Amend subrule 79.1(8) as follows:

79.1(8) *Drugs.* The amount of payment shall be based on several factors, subject to the upper limits in 42 CFR 447.500 to 447.520 as amended to ~~October 7, 2008~~ May 16, 2012. The Medicaid program relies on information published by Medi-Span to classify drugs as brand-name or generic. Specialty drugs include biological drugs, blood-derived products, complex molecules, and select oral, injectable, and infused medications identified by the department and published on the specialty drug list.

a. ~~Reimbursement~~ Until February 1, 2013, or federal approval of the reimbursement methodology provided in paragraph 79.1(8)*"c,"* whichever is later, reimbursement for covered generic prescription drugs shall be the lowest of the following, as of the date of dispensing:

(1) The estimated acquisition cost, defined:

1. For covered nonspecialty generic prescription drugs, as the average wholesale price as published by Medi-Span less 12 percent, plus the professional dispensing fee specified in paragraph ~~*"g."*~~ 79.1(8)*"i"*; or

2. For covered specialty generic prescription drugs, as the average wholesale price as published by Medi-Span less 17 percent, plus the professional dispensing fee specified in paragraph ~~*"g."*~~ 79.1(8)*"i."*

(2) The maximum allowable cost (MAC), defined as the upper limit for multiple source drugs established in accordance with the methodology of the Centers for Medicare and Medicaid Services as described in 42 CFR 447.514, plus the professional dispensing fee specified in paragraph ~~*"g."*~~ 79.1(8)*"i."*

(3) The state maximum allowable cost (SMAC), defined as the average wholesale acquisition cost for a generic drug (the average price pharmacies pay to obtain the generic drug as evidenced by purchase records) adjusted by a multiplier of 1.2, plus the professional dispensing fee specified in paragraph ~~*"g."*~~ 79.1(8)*"i."*

(4) The submitted charge, representing the provider's usual and customary charge for the drug.

b. ~~Reimbursement~~ Until February 1, 2013, or federal approval of the reimbursement methodology provided in paragraph 79.1(8)*"d,"* whichever is later, reimbursement for covered brand-name prescription drugs shall be the lower of the following, as of the date of dispensing:

(1) The estimated acquisition cost, defined:

1. For covered nonspecialty brand-name prescription drugs, as the average wholesale price as published by Medi-Span less 12 percent, plus the professional dispensing fee specified in paragraph ~~*"g."*~~ 79.1(8)*"i"*; or

2. For covered specialty brand-name prescription drugs, as the average wholesale price as published by Medi-Span less 17 percent, plus the professional dispensing fee specified in paragraph ~~*"g."*~~ 79.1(8)*"i."*

(2) The submitted charge, representing the provider's usual and customary charge for the drug.

c. Effective February 1, 2013, or upon federal approval, whichever is later, reimbursement for covered generic prescription drugs and for covered nonprescription drugs shall be the lowest of the following, as of the date of dispensing:

(1) The average actual acquisition cost (AAC), determined pursuant to paragraph 79.1(8)*"k,"* plus the professional dispensing fee determined pursuant to paragraph 79.1(8)*"j."*

(2) The maximum allowable cost (MAC), defined as the specific upper limit for multiple source drugs established in accordance with the methodology of the Centers for Medicare and Medicaid Services as described in 42 CFR 447.514, plus the professional dispensing fee determined pursuant to paragraph 79.1(8)*"j."*

(3) The submitted charge, representing the provider's usual and customary charge for the drug.

d. Effective February 1, 2013, or upon federal approval, whichever is later, reimbursement for covered brand-name prescription drugs shall be the lower of the following, as of the date of dispensing:

(1) The average actual acquisition cost (AAC), determined pursuant to paragraph 79.1(8)*"g,"* plus the professional dispensing fee determined pursuant to paragraph 79.1(8)*"j."*

(2) The submitted charge, representing the provider's usual and customary charge for the drug.

~~*c.*~~ *e.* No payment shall be made for sales tax.

~~*d.*~~ *f.* All hospitals that wish to administer vaccines which are available through the vaccines for children program to Medicaid members shall enroll in the vaccines for children program. In lieu of payment, vaccines available through the vaccines for children program shall be accessed from the department of public health for Medicaid members. Hospitals receive reimbursement for the administration of vaccines to Medicaid members through the DRG reimbursement for inpatients and APC reimbursement for outpatients.

~~*e.*~~ *g.* ~~The~~ Until February 1, 2013, or federal approval of the reimbursement methodology provided in paragraph 79.1(8)*"c,"* whichever is later, the basis of payment for nonprescription drugs shall be the same as specified in paragraph 79.1(8)*"a"* except that the department shall establish a maximum allowable reimbursable cost for these drugs using the average wholesale prices of the chemically equivalent products available. The department shall set the maximum allowable reimbursable cost at the median of those average wholesale prices. No exceptions for higher reimbursement will be approved.

~~*f.*~~ *h.* An additional reimbursement amount of one cent per dose shall be added to the allowable ~~ingredient~~ cost of a prescription for an oral solid if the drug is dispensed to a patient in a nursing home in unit dose packaging prepared by the pharmacist.

~~*g.*~~ *i.* For services rendered on or after August 1, 2011, and before February 1, 2013, or federal approval of the professional dispensing fee provided in paragraph 79.1(8)*"j,"* whichever is later, the professional dispensing fee is $6.20 or the pharmacy's usual and customary fee, whichever is lower.

j. Effective February 1, 2013, or upon federal approval, whichever is later, professional dispensing fees shall be amounts determined by the department based on a survey of Iowa Medicaid retail pharmacy providers' costs of dispensing drugs to Medicaid beneficiaries. For services rendered on or after February 1, 2013, and after federal approval, the dispensing fee for all drugs shall be $10.02.

k. For purposes of this rule, average actual acquisition cost (AAC) is defined as retail pharmacies' average prices paid to acquire drug products. Average AAC shall be determined by the department based on a survey of invoice prices paid by Iowa Medicaid retail pharmacies. Surveys shall be conducted at least once every six months, or more often at the department's discretion. The average AAC shall be calculated as a statistical mean based on one reported cost per drug per pharmacy. The average AAC determined by the department shall be published on the Iowa Medicaid enterprise Web site. If no current average AAC has been determined for a drug, the wholesale acquisition cost (WAC) published by Medi-Span shall be used as the average AAC.

~~*h.*~~ *l.* For purposes of this subrule, "equivalent products" shall be those that meet therapeutic equivalent standards as published in the federal Food and Drug Administration document, "Approved Prescription Drug Products With Therapeutic Equivalence Evaluations."

~~*i. Pharmacies and providers that are enrolled in the Iowa Medicaid program shall make available drug acquisition cost information, product availability information, and other information deemed necessary by the department to assist the department in monitoring and revising reimbursement rates subject to 79.1(8)"a"(3) and 79.1(8)"c" and for the efficient operation of the pharmacy benefit.~~

~~(1) Pharmacies and providers shall produce and submit the requested information in the manner and format requested by the department or its designee at no cost to the department or its designee.~~

~~(2) Pharmacies and providers shall submit information to the department or its designee within 30 days following receipt of a request for information unless the department or its designee grants an extension upon written request of the pharmacy or provider.~~

~~*j.*~~ *m.* Savings in Medicaid reimbursements attributable to the SMAC shall be used to pay costs associated with determination of the SMAC, before reversion to Medicaid.

~~*k.*~~ *n.* Payment to physicians for physician-administered drugs billed with Healthcare Common Procedure Coding System (HCPCS) Level II "J" codes, as a physician service, shall be pursuant to physician payment policy under subrule 79.1(2).

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